

### REMARKS

A new drawing (Figure 3) has been submitted herewith. Page 6 and page 52 of the specification and claim 53 have been amended accordingly.

Claim 31 has been amended to more clearly point out and distinctly claim the subject matter that Applicants regard as the present invention by adding the limitation of claim 47 to claim 31. Additional support for this amendment can be found at page 29, lines 8-10.

Claim 36 has been amended to include specific protease inhibitors. Support for the amendment can be found in claims 31 and 47.

Claims 41 and 42 have been amended to make clear, respectively, that the delivery system contains the protease inhibitor and the percentage refers to weight percent of the skin care composition. Support for the amendments can be found at page 29, lines 25-31 and page 32, lines 6-9.

Claim 47 has been canceled without prejudice.

These amendments do not contain new matter. Entry is believed to be proper and respectfully requested.

### DRAWINGS

The drawings are objected to under 37 C.F.R. §1.83(a). The Office Action stated that leg cuff and skin care composition disposed on the topsheet in a plurality of stripes that are separated by a plurality of stripes having no skin care composition must be shown or the feature(s) should be canceled from the claims.

Section 1.83(a) of 37 C.F.R. states that:

“However, conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box).” (emphasis added)

Applicants respectfully point out that leg cuffs are conventional features in an absorbent article, such as a diaper. Therefore, a detailed illustration of the leg cuffs is not essential for a proper understanding of the present invention. Moreover, leg cuffs are illustrated in Figure 1 as elongated rectangles labeled “550”, which are clearly identified as leg cuffs on page 5, lines 3-4 of the specification. In view of the above, Applicants respectfully submit that, with respect to the leg cuffs, the requirement of 37 C.F.R. §1.83(a) is fully met.

Applicants submit herewith a new drawing, Figure 3, to illustrate the skin care composition being disposed on the topsheet in the form of a plurality of stripes, which is fully supported by page 52, lines 15-19 of the specification. No new matter is added.

Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the objections.

### CLAIM REJECTIONS

#### Claim Rejection under 35 USC §112, First Paragraph

Claim 47 is rejected under 35 USC §112, first paragraph, as containing subject matter which is not described in the specification. The Office Action stated that an article comprising from about 0.001% to about 30% by weight of the protease inhibitor is not disclosed.

Claim 47 has been canceled without prejudice, rendering this rejection moot. Applicants respectfully request withdrawal of this rejection.

#### Claim Rejections under 35 USC §112, Second Paragraph

Claims 31-53 are rejected under 35 USC §112, second paragraph, as being indefinite. Claim 31 is rejected because the term "a protease inhibitor" and the phrase "hexamidine and its salts" or "pentamidine and its salts" are not consistent. Claim 42 is rejected because it is unclear if the protease inhibitor is within or separate from the delivery system.

Claim 31 has been amended to resolve the inconsistencies by using the Markush language. Claim 41 has been amended to make clear that the delivery system contains the protease inhibitor and the percentage refers to weight percent of the skin care composition. Support for this amendment can be found at page 29, lines 25-31.

Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections.

#### Claim Rejections under 35 USC §103 over Roe in View of Kasahara

Claims 31-33, 36 and 41-53 are rejected under 35 USC §103 as being unpatentable over Roe (US 5,607,760) in view of Kasahara et al. (JP 04-182,423). With respect to claims 31-33, 36, 41-44, 51 and 52, the Examiner stated that Roe teaches a diaper containing a topsheet coated with a semisolid lotion and the lotion may be applied to the topsheet non-uniformly where portions of the topsheet do not have lotion on it. The Examiner acknowledged that Roe is silent regarding lotion containing a protease inhibitor. Kasahara teaches protease inhibitors in the form of a lotion or emulsion, and the inhibitors include benzamidine and derivatives thereof. The Examiner considered benzamidine to be an equivalent of pentamidine, functional wise; the Examiner attributed the active/functional group to be the benzamidine structure. The Examiner also considered IC<sub>50</sub> to be an inherent property of the protease inhibitor. With respect to claims 45, 46 and 50, the Examiner suggested that Roe discloses lotion on the topsheet, therefore, it will be transferred onto the skin of the wearer by heat or pressure.

Applicants respectfully traverse.

First, Applicants point out that the Office Action did not reject the protease inhibitor 4-(2-aminoethyl)-benzenesulfonylfluoride hydrochloride. Therefore, Applicants assume that the Examiner considered this protease inhibitor, as claimed in claim 31, allowable.

Second, Applicants submit that benzamidine and pent- or hex-amidine have significantly different structures, which contribute to significantly different inhibitory activities. The attached Rule 132 Declaration by Dr. Osborne illustrates these differences. Referring to the data in Dr. Osborne's Declaration, it is clear that the benzamidine disclosed by Kasahara is vastly different from the pent- or hex-amidine of the present invention, structurally and functionally.

Thus, Applicants submit that the combination of Roe and Kasahara in no way teach or suggest the presently claimed invention directed to particular protease inhibitors. More importantly, the combined teaching of Roe and Kasahara would not result in an absorbent article as claimed herein.

Additionally, Applicants have added the limitation of claim 47 to claim 31 such that the claimed article contains a select amount of these protease inhibitors to provide the desired benefits. There is no teaching or suggestion in the cited references of this limitation.

Similarly, claim 36 is directed to an article containing a select amount of specific protease inhibitors to provide the desired benefits.

Therefore, Applicants submit that claim 31 and its dependent claims 32-33, 41-46, 48-53 as well as independent claim 36 are in condition for allowance and this 103 rejection thereof should be withdrawn.

#### Claim Rejection under 35 USC §103 over Roe And Kasahara in View of Van Rijswijck

Claim 53 is rejected under 35 USC §103 as being unpatentable over Roe and Kasahara in view of Van Rijswijck (US 6,120,488). The Examiner stated that Roe and Kasahara disclose the use of skin care composition disposed on the topsheet, but fails to disclose the skin care composition in the form of stripes on the topsheet; Van Rijswijck discloses the use of skin care composition on the topsheet in a plurality of stripes.

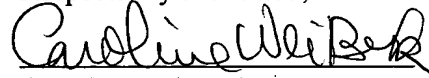
Applicants point out that claim 53 depends from claim 31, thus, contains all the limitations of claim 31. Applicants respectfully submit that because the Examiner failed to establish obviousness regarding the broader claim, the Examiner's reliance on a reference that supposedly teaches a specific limitation of the dependent claim is improper. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

The above represents a complete response to the Final Office Action dated June 7, 2002. Reconsideration, withdrawal of rejection and allowance of claims 31-33, 36, 41-46, 48-53 are respectfully requested.

October 31, 2002  
Customer No. 27752

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

IN THE SPECIFICATION

**On page 6, Please amend “BRIEF DESCRIPTION OF THE DRAWINGS” as indicated.**

**Figure 1** is a schematic illustration of an absorbent article in the form of a diaper according to the present invention.

**Figure [2] 2A** is a side view showing placement of a skin analog used in the skin care composition transfer test and/or the protease inhibitor transfer test.

**Figure [3] 2B** is a plan view showing placement of the skin analog used in the skin care composition transfer test and/or the protease inhibitor transfer test.

**Figure 3 is an absorbent article in the form of a diaper, which has a plurality of lotion stripes.**

**Please amend the paragraph beginning at page 52, line 15, as indicated.**

In one preferred embodiment of the present invention (as shown on Figure 3), the topsheet of the articles utilized will comprise stripes 30 of protease-containing composition that run in the article's longitudinal direction. These longitudinal stripes (or spirals) are separated by [longitudinal stripes] open areas where little or no protease-containing composition is applied to the topsheet. In these embodiments, each stripe of composition will typically have a width of from about 0.1 in. to about 0.75 in., more typically from about 0.1 in. to about 0.5 in., and the width of the stripes containing no composition will typically be from about 0.1 in. to about 1 in., more typically from about 0.15 to about 0.5 in. These ranges are applicable to typical infant diaper designs. For larger products such as adult incontinent products, these ranges may be higher

IN THE CLAIMS

Please amend the following claims:

31. (Twice Amended) An absorbent article at least a portion of which comprises a protease inhibitor, wherein the protease inhibitor comprises from about 0.001% to about 30% by weight of the article; the protease inhibitor has an IC<sub>50</sub> of about 500 μM or less, as measured by a General Fecal Protease Method[.]; and [wherein] the protease inhibitor is selected from the group consisting of 4-(2-aminoethyl)-benzenesulfonylfluoride hydrochloride, hexamidine and its salts, [or] pentamidine and its salts, and mixtures thereof.
36. (Amended) An absorbent article at least a portion of which comprises a protease inhibitor, wherein the protease inhibitor comprises from about 0.001% to about 30% by weight of the article; an extract of at least a portion of the absorbent article produces a 20% reduction in substrate hydrolysis by a proease in an Absorbent Article Test Method; and the protease inhibitor is selected from the

group consisting of 4-(2-aminoethyl)-benzenesulfonyl fluoride hydrochloride, hexamidine and its salts, pentamidine and its salts, and mixtures thereof.

41. (Amended) The article of claim 31, wherein the absorbent article comprises a delivery system [for] and the delivery system contains the protease inhibitor.
42. (Amended) The article of claim 41, wherein the delivery system is a skin care composition [which comprises] and the protease inhibitor comprises from about 0.01% to about 50% by weight of the skin care composition [protease inhibitor].

**Please cancel claim 47 without prejudice.**

53. (Amended) The article of claim 51, wherein the skin care composition is disposed on the topsheet in a plurality of stripes [that are separated by a plurality of stripes having no skin care composition].